DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Central Region M3013M

Food and Drug Administration
Waterview Corporate Center
10 Waterview Blvd., 3rd Floor
Parsippany, NJ 07054

Telephone (973) 526-6008

WARNING LETTER

Certified Mail
Return Receipt Requested

File # 99-NWJ-40

September 28, 1999

George Gillert
President
Atalanta Corporation, Inc.
1 Atalanta Plaza
Elizabeth, NJ 07206

Dear Mr. Gillert:

During a July 20-21, 1999 inspection of Monarch Seafood, Inc., located at 80 Broadway, Jersey City, NJ 07306, our Investigator documented violations of Section 123 of Title 21, Code of Federal Regulations. The violations of the Fish and Fishery Product (HACCP) regulations cause your products -- fresh tuna, mahi mahi, marlin and wahoo -- to be in violation of Section 402(a)(4) of the Federal Food, Drug and Cosmetic Act (the Act), whereby your products were prepared, packed or held under insanitary conditions whereby they may have rendered injurious to health.

The inspectional observations of concern were:

- You must have a written HACCP plan to control any food safety hazards that are reasonably likely to occur, in order to comply with 21 CFR 123.6(b). You firm does not have a HACCP plan for scombrotoxin-forming species of fish (i.e., fresh mahi mahi, tuna, wahoo and marlin) to control the food safety hazard related to histamine formation.

- You must have a HACCP plan that lists the critical control points, critical limits and monitoring procedures for each critical control point in order to comply with 21 CFR 123.6(c)(2), (3) and (4). For example, monitoring critical limits for time and temperature, at appropriate critical control points such as receipt, processing and storage in order to control histamine development. Moreover, you do not have monitoring records to document your monitoring procedures in order to comply with 21 CFR123.6(c)(7).

- You must take appropriate corrective action when a deviation from a critical limit occurs in order to comply with 21 CFR 123.7(a). For example, your firm was observed adding ice to product when the temperature was at 50 F. Adding ice alone, without evaluating whether the product is adulterated or injurious to health is not an appropriate corrective action. Moreover, you must fully document, via recordkeeping, all corrective action taken in order to comply with 21 CFR 123.7(d).

Similar instances of these observations were previously reported to you in a letter from this office, dated March 26, 1999, referencing an inspection conducted by the New Jersey Department of Health, under contract with this Agency. No response in any form (i.e., verbal, written, etc.) to that letter was received by this office.

The above items are not intended to be an all-inclusive list of violations. As a manufacturer of human food, you are responsible for assuring that your overall operation and the food products themselves are in compliance with the law.

You should take prompt action to correct the above violations and to establish procedures whereby such violations do not recur. Failure to do so may result in regulatory action without further notice such as seizure and /or injunction.

You should notify this office in writing within 15 working days' receipt of this letter of the steps you have taken to bring your firm into compliance with the law. Your response should include each step being taken that has been taken or will be taken to correct the violations and prevent their recurrence. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time frame within which the corrections will be completed. Please include copies of any available documentation demonstrating that corrections have been made.

Your reply should be directed to the Food and Drug Administration, Attention: Kirk D. Sooter, Compliance Officer, at the address and telephone number above.

Sincerely yours,

Edward H. Wilkens, for
Douglas I. Ellsworth
District Director